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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|------------------------------------|------------------|
| 10/047,608 | 01/14/2002 | Leonard Bell | ALXN-P01-059 | 5748 |
| 7590 01/03/2006 Fish & Neave IP Group of Ropes & Gray LLP One International Place Boston, MA 02110 | | | EXAMINER VANDERVEGT, FRANCOIS P | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1644 | |

DATE MAILED: 01/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|----------------------------------|-------------------------------|--|
| Office Action Summary | Application No. 10/047,608 | Applicant(s) BELL, LEONARD | |
| | Examiner F. Pierre VanderVegt | Art Unit 1644 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2005 and 07 October 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-32 and 34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-32 and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

This application claims the benefit of the filing date of provisional application 60/262,540.

Claims 1-26, 33 and 35-41 have been canceled.

Claims 27-32 and 34 are currently pending and are the subject of examination in the present Office Action.

In view of Applicant's amendments filed August 16, 2005 and October 7, 2005, no outstanding ground of rejection is maintained.

The following new grounds of rejection have been necessitated by Applicant's amendment.

Applicant's arguments with respect to claims 27-32 and 34 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 27-32 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Fitch et al (Circulation [1999] 100:2499-2506, cited on form PTO-1449; of record) in view of Gori et al (Thromb. Haemost [1999] 81:589-593; U on form PTO-892, newly cited).

The claims are drawn to a method of prophylaxis against myocardial infarction in a patient undergoing cardiopulmonary bypass surgery. The method includes the steps of administering a bolus of an anti-inflammatory agent to the patient prior to or at the start of surgery and a subsequent administration of additional anti-inflammatory agent to the patient. It is noted that there is no requirement in the claims that the anti-inflammatory agent administered in step a) is the same as the anti-inflammatory agent administered in step b).

Fitch teaches the administration of a bolus of heparin to patients about to undergo cardiopulmonary bypass surgery (page 2500, first new paragraph of second column in particular). Heparin is commonly referred to as an anti-coagulant, but also serves as an anti-inflammatory agent, as evidenced by Gori. Gori discloses that heparin treatment is associated with a decrease of high plasma levels of tissue factor, which is an inflammatory agent, and monocyte procoagulant activity. Gori further

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discloses that “[t]hese actions of heparin may play a role in determining the antithrombotic and antiinflammatory properties of this drug (Abstract and page 592, end of column 1 in particular). Gori further discloses that “heparin reduces the risk of myocardial infarction and new ischemic events) (page 592, first column in particular). accordingly, Gori discloses that anti-inflammatory action is an inherent property of heparin.

Fitch further teaches the administration of a humanized single chain monoclonal antibody directed to human complement component C5 (h5G1.1-scFv) to the patients subsequent to the administration of heparin when the “activated clotting time was greater than 400 seconds,” infusing the antibody over a 10-minute period (page 2500, first new paragraph of second column in particular). Fitch teaches that the nature of the surgery was “coronary artery bypass surgery” (Title and Abstract in particular). While Fitch does not teach the amino acid sequence of the h5G1.1-scFv antibody used in the method, it is noted that the h5G1.1-scFv antibody used by Fitch is the same antibody as the one used in the instant specification. Therefore, the sequence of the antibody is an inherent property that is the same between the antibody of Fitch and that which has been further characterized in the instant specification by disclosure of the amino acid sequence. Applicant is reminded that further characterization of an otherwise old product does not distinguish the product from the prior art because the product itself remains the same, regardless of the method of characterization. See *Ex parte* Novitski (Bd. Pat. App. & Int.) 26 USPQ2d 1389. The prior art teaching anticipates the claimed invention.

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Conclusion

3. No claim is allowed.

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

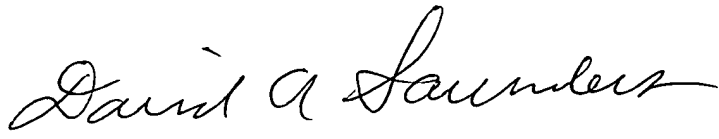
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00 and Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

F. Pierre VanderVegt, Ph.D.
Patent Examiner
December 23, 2005


DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 182-1644